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IN THE APPLICATION

OF

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AND

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FOR AN

I.V. SOLUTION BAG WITH A NEEDLELESS PORT

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I.V. SOLUTION BAG WITH A NEEDLELESS PORT

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention generally relates to intravenous (I.V.) solution bags. More specifically, the present invention relates to an I.V. solution bag adapted for receiving fluid materials from needleless administering devices, for limiting or preventing contamination resulting from the administration of fluid materials, and for limiting an amount or volume of a fluid material which may become airborne from disengagement of a needleless administering device from the I.V. solution bag.

2. DESCRIPTION OF THE RELATED ART

A number of valve devices, containers for receiving fluids, and I.V. solution bags have been devised for receiving and/or regulating the reception, mixing, administration, and/or flow of fluids. The classic I.V. solution bag is generally two polymeric or plastic sheets superimposed on each other and sealed together at their periphery defining a receiving chamber therein. The I.V. solution bag generally has an access port

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adapted for receiving fluid materials from an administering device, such as a syringe, having a needle.

With OSHA pushing the medical field to go to a needle free system for safety and disposal reasons, the present invention helps health professionals to accomplish certain medical tasks, such as mixing medications or administering fluid materials into I.V. solution bags, without the hazards of getting needle sticks. Devices exist to insert into a vial of medication which have a luer lock system on them for pulling up medications, but then the health professional has to put a needle on the syringe and use that needle to administer the medication into an I.V. bag. Health professionals have stuck themselves when administering medications into I.V. bags by the needle going through the rubber stopper at the wrong angle.

For example, U.S. Patent No. 4,447,230, issued May 8, 1984 to Gula, et al., describes an I.V. administration set assembly which is capable of introducing fluid from a plurality of sources of I.V. fluids into a patient and which allows the various sources of fluid to be easily attached and detached from the assembly without the necessity for intervening safety steps, and yet without any possibility of air or bacteria being introduced through the system into the patient. An air-eliminating filter and check valves are also described.

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U.S. Patent No. 4,838,875, issued June 13, 1989 to Somor, describes an apparatus for I.V. administration of fluid by injecting same using a needleless syringe directly into the hollow portion of the apparatus through an opening therein. A normally closed backflow check valve device, having a component thereof acting as a means for receiving the fluid by engagement to the syringe, is permanently sealed into the opening in the hollow portion of the apparatus. To protect the opening into the apparatus from contamination, the apparatus is capped by a double luer locking cap. This is accomplished by using a cap structure wherein the cap, which will ultimately re-cover the opening, is locked into and protected by the cap which initially covers the opening, and then discarding this initial cap after the apparatus has been filled.

U.S. Patent No. 5,059,173, issued October 22, 1991 to Sacco, describes an I.V. administration set-up that includes a main flow line having a capped spike for receiving an I.V. bag at the top end thereof and a needle unit at the bottom end thereof for injecting fluids into a patient. The main flow line has a first drip chamber mounted therein which is capable of administering fluids at a first flow rate.

U.S. Patent No. 5,439,451, issued August 8, 1995 to Collinson, et al., describes a medical backcheck valve that

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includes a hollow housing containing an upwardly biased piston assembly for controlling liquid flow therethrough. The piston assembly comprises a substantially rigid plug having one end protruding from the upper end of the housing, and a flexible sheath covering having a relatively small diameter upper end surrounding the plug, a main seal for controlling flow through said first flow space, and a tubular lower end, secured at the bottom of the housing, for preventing liquid from entering within the covering.

U.S. Patent No. 5,445,630, issued August 29, 1995 to Richmond, describes a hollow spike having a pointed distal end, a proximal end, and a luer fitting positioned in the proximal end of the spike to engage a complementary fitting associated with another IV component. A reflex valve is disposed in the luer fitting to permit fluid flow through the spike when a complementary fitting is connected to the luer fitting of the spike, and to prevent fluid flow through the spike when no fitting is engaged with the fitting of the spike.

U.S. Patent No. 5,728,086, issued March 17, 1998 to Niedospial, Jr., describes a universal, flexible container with multiple access ports having first and second polymeric sheets sealed together at their periphery defining an interior reservoir, a first access member at the center of the bottom

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portion equipped with tubing means and one-way her slip stopcock, a needle access member located on one side of the first access member, and a spike access member located on the other side of the first access member.

U.S. Patent No. 5,782,816 issued on July 21, 1998 to Werschmidt et al., and a web page published by Maximus Medical Products, Inc. titled "A full-line of needlefree products to meet your needs...The MaxPlus™ Needleless Connector". published in July 2003, disclose a bi-directional valve. The valve is a connector adapted to facilitate medicinal access into an intravenous tube that includes a housing having a base and a cap defining a channel through the housing. A valve element is disposed in the channel that includes a plug and a shaft that biases the plug into engagement with the housing.

U.S. Patent No. 6,063,062, issued May 16, 2000 to Paradis, describes a universal luer activatable and swabable antireflux valve formed by a housing having an inlet and an inwardly biased and circumferentially open flexible seal depending from the inlet to engage and seal a fitting as it enters the inlet. A stationary probe within the housing extends axially from an outlet to the inlet, with the probe having a passageway thereinto connected to the outlet and the input is sealed when there is a reflux of fluid into the outlet.

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U.S. Patent No. 6,068,617, issued May 30, 2000 to Richmond, describes an I.V. port comprising an I.V. container, at least one port body extending from the I.V. container, a valve body operably engaged within the port body and defining a fluid passageway for permitting fluid flow into and out of the I.V. container, and a valve member positioned in the valve body for selectively blocking fluid through the valve body. The valve member defines an outer periphery that is uninterrupted within the periphery, and is disposed in the valve body and biased to a closed configuration, wherein a passageway for fluid communication is not established through the valve body, and is movable to an open configuration when a mating component is engaged, wherein two-way fluid communication through the valve body is permitted.

U.S. Patent No. 6,106,502, issued August 22, 2000 to Richmond, describes an I.V. set including a drip chamber having a top end and a bottom end. A spikeless connector covers the top end, and an I.V. tube is connected to the bottom end of the drip chamber. The end of the I.V. tube opposite the drip chamber is engaged with a needleless/spikeless connector. Thereby, a needleless/spikeless I.V. set is rendered. A reflux valve including a deformable valve member and reciprocating

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valve element is also disclosed for use in conjunction with the needleless/spikeless I.V. connectors.

U.S. Patent No. 6,156,025, issued December 5, 2000 to Niedospial, Jr., et al., describes a twist valve in communication with a pre-filled flexible container and includes a proximal part and a distal part each having a fluid inlet and a fluid outlet. The fluid outlet of the proximal part is blocked with a stopper in the distal part when the twist valve is in the closed position, and is unblocked by the stopper when the twist valve is in the open position.

U.S. Patent No. 6,299,132, issued October 9, 2001 to Weinheimer, et al., describes a reflux valve engageable with corresponding structure, such as with another corresponding valve or instrument. The reflux valve includes an actuator which is located in, and shiftable in, a valve body. When the corresponding structure is engaged with the actuator, the actuator shifts in the valve body, and pushes a valve stem out of engagement with a valve seat. As a result, liquid is allowed to flow, in one direction, through the actuator, past the valve seat, along an area adjacent a periphery of the valve stem, and out the valve body. Preferably, when the valve stem is unseated from the valve seat, liquid can also flow in an opposite direction.

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U.S. Patent Application No. 2002/0128628 published on September 12, 2002 to Fathallah, M.A. discloses a drug delivery system. The system stores a beneficial agent and mixes it with a component in a reservoir and then delivers the mixture to a patient.

U.S. Patent Application No. 2002/0147440 published on October 10, 2002 to Samolyk, K.A. discloses a method of autologous blood recovery. The invention is directed to a blood bag system comprising a sterile bag of bio-compatible material with an infusion port at the upper end of the bag, an outlet port at the lower end of the bag, a hemo-concentrator, a pair of inlet tubes connected to the hemo-concentrator and a pair of outlet tubes fluidly connected to an outlet port on the hemo-concentrator.

U.S. Patent No. 6,520,932, issued February 18, 2003 to Taylor, describes an in-line drug delivery pack that connects in-line with an I.V. line and allows for the mixing of diluent with a drug reagent to be delivered to the patient. An internal drug bed bypass mechanism is tailored to apportion diluent flow between the bypass and the drug bed. The apportionment is selected to achieve a solution concentration suitable for I.V. administration as the dried reagent is dissolved.

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WO95/32748, published December 7, 1995 to Nathan Palestrant, describes a self-sealing valve device for an angiographic catheter including a housing having a first end adapted to form a luer lock connection with the proximal end of the angiographic catheter. A central bore extends between the first end of the housing and an opposing second end, and a deformable slit seal is supported across the central bore to selectively seal the proximal end of the catheter. The second end of the housing is provided with a female luer lock fitting for receiving the conical tip of a syringe, stopcock, or the like, and forming a pressure tight connection therebetween.

None of the above inventions and patents, taken either singly or in combination, is seen to describe the instant invention as claimed. Thus, an I.V. solution bag adapted for receiving fluid materials administered from needleless administering devices, for limiting or preventing contamination resulting from the administration of fluid materials, and for limiting an amount or volume of a fluid material which may become airborne from disengagement of a needleless administering device from the I.V. solution bag is desired.

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SUMMARY OF THE INVENTION

The present invention is an I.V. solution bag adapted for receiving fluid materials administered from needleless administering devices, for limiting or preventing contamination resulting from the administration of fluid materials, and for limiting an amount or volume of a fluid material which may become airborne from disengagement of a needleless administering device from the I.V. solution bag. The I.V. solution bag defines a receiving chamber therein and has at least one first access port adapted for permitting fluid materials to be administered into or withdrawn from the receiving chamber.

The I.V. solution bag also has a positive pressure valve device secured at the first access port and in fluid communication with the receiving chamber, and may further have a handle adapted for hanging the I.V. solution bag.

The valve device has a housing and a valve member disposed within the housing. The housing has an inlet end, an outlet end and a housing body such that the housing defines a fluid passageway therethrough. The inlet end of the housing is adapted for engagement with outlet ends of the needleless administering devices, and the outlet end of the housing is in fluid communication the receiving chamber.

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The valve member has an inlet end and a deformable body, both disposed within the housing. The inlet end of the valve member is flush with the inlet end of the housing such that a deformable seal is defined and formed to limit or prevent contamination from entering the receiving chamber through the fluid passageway. The valve member is biased to a closed configuration wherein the fluid passageway is closed, and is movable to an open configuration wherein the fluid passageway is open to permit fluid materials administered by the needleless administering devices to flow through the fluid passageway.

Accordingly, it is a principal object of the invention to provide an I.V. solution bag adapted for receiving fluid materials administered from needleless administering devices.

It is another object of the invention to provide an I.V. solution bag for limiting or preventing contamination resulting from the administration of fluid materials from needleless administering devices into the I.V. solution bag.

It is a further object of the invention to provide an I.V. solution bag for limiting an amount or volume of a fluid material that may become airborne from disengagement of a needleless administering device from the I.V. solution bag.

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It is an object of the invention to provide improved elements and arrangements thereof for the purposes described which is inexpensive, dependable and fully effective in accomplishing its intended purposes.

These and other objects of the present invention will become readily apparent upon further review of the following specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an environmental, frontal view of an intravenous (I.V.) solution bag of the present invention.

Fig. 2 is a perspective, bottom view of the I.V. solution bag of Fig. 1.

Fig. 3 is a perspective, bottom view of the I.V. solution bag of the present invention having another embodiment of the valve device.

Fig. 4 is a perspective view of the valve device of Fig. 1.

Fig. 5 is a cross-sectional view of the valve device taken along 5-5 of Fig. 4.

Fig. 6 is an environmental, cross-sectional view of the valve device of Fig. 5, showing the direction of flow of fluid material through the fluid passageway of the valve device.

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Similar reference characters denote corresponding features consistently throughout the attached drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figs. 1-6, the present invention is an intravenous (I.V.) solution bag **10** adapted for receiving fluid materials administered from needleless administering devices, such as a syringe **12** having an outlet end **14** and no needle, for minimizing or preventing contamination resulting from the administration of fluid materials, and for limiting an amount or volume of a fluid material which may become airborne from disengagement of a needleless administering device from the I.V. solution bag **10**. The present invention also allows for fluids to be withdrawn from the I.V. solution bag **10**, for mixing with powdered medications, with a needleless fluid collection device.

As shown in Figs. 1-3, the I.V. solution bag **10** has a receiving chamber **22**, a first access port **24**, a second access port **26**, a positive pressure valve device **50** securely sealed at the first access port **24**, and a spike access port extension **40** securely sealed at the second access port **26**. The I.V. solution bag **10** may further have a handle **80** adapted for hanging the I.V. solution bag **10** upon a secured or standing structure **19**.

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The I.V. solution bag **10** is generally two polymeric or plastic sheets superimposed on each other and sealed together at their periphery defining a receiving chamber **22** therein. The I.V. solution bag **10** may be a universal, flexible, I.V. solution bag, but may also be a semi-rigid or rigid solution bag.

The I.V. solution bag **10** may be manufactured in many useful sizes, such as 500 ml or any other size known in the art, to receive and/or contain a predetermined volume or amount of I.V. solution, medication in the form of liquids or gels, cell or tissue culture, other fluid materials, and the like. As an example of the usage of the present invention, the I.V. solution bag **10** may be manufactured to contain or store, before usage, a predetermined volume of I.V. solution, and then, when needed or desired, a certain volume or amount of medication may be administered or added to the stored I.V. solution by the syringe **12** through the fluid passageway **68** defined by the housing **60** of the positive pressure valve device **50**.

As best shown in Figs. 2 and 3, the first access port **24** and second access port **26** are located about one another toward the center of the bottom portion **28** of the I.V. solution bag **10**. Alternatively, one or both of the access ports **24,26** may be

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located at a side portion **30,32** and/or top portion **34** of the I.V. solution bag **10**.

The spike access port extension **40**, which extends downwardly from the bottom portion **28** of the I.V. solution bag **10**, is securely sealed at the periphery of the second access port **26**. As best shown in Figs. 2 and 3, the spike access port extension **40** has an inlet end **42**, a generally hollow, tubular body **44**, an engaging flange **46** located externally between the inlet end **42** and tubular body **44** and extending outwardly from the axis of the spike access port extension **40**, and a puncturable membrane or seal **48** located internally between the inlet end **42** and tubular body **44**. The spike access port extension **40** is adapted for engagement or attachment with a receiving device, such as an I.V. tubing **16**, a catheter, or other receiving devices known in the art. For example and as shown in Fig. 1, an inlet end **18** of the I.V. tubing **16** may be inserted through the inlet end **42** and into the tubular body **44** such that the inlet end **18** pierces and is held there by the puncturable seal **48**.

The positive pressure valve device **50**, which extends through the first access port **24** and downwardly from the bottom portion **28** of the I.V. solution bag **10**, is securely sealed at the periphery of the first access port **24**. As best shown in

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Figs. 4-6, the valve device **50** has a housing **60** and a valve member **70** disposed within the housing **60**. The valve device **50** is in fluid communication with the receiving chamber **22** and fluids contained in the receiving chamber **22** such that the fluid material administered from the syringe **12** will travel through the fluid passageway **68** and into the receiving chamber **22**. As shown in detail in Figs. 4-6, an example of the valve device **50** of the present invention is the MaxPlus™ needleless connector of Maximus Medical Products, Inc. The present valve device 50 is disclosed fully in United States Patent Number 5,782,816 issued to Werschmidt et al. on July 21, 1998, the disclosure of which is hereby incorporated by reference in its entirety. The MaxPlus™ needleless connector has minimal dead space, and is latex-free, DEHP-free and even MRI safe. Also, the MaxPlus™ needleless connector is a positive pressure device that will flush fluid at a specific rate. Alternatively, a backflow check valve device similar to the MaxPlus™ needleless connector and having substantially similar specifications and/or details of the described valve device **50**, may be used in the present invention.

As best shown in Figs. 5 and 6, the housing **60** has an inlet end **62**, an outlet end **64** and a housing body **66** extending from

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the inlet end **62** to the outlet end **64** of the housing **60** such that the housing **60** defines the fluid passageway **68** therethrough. The inlet end **62** of the housing **60** is adapted for engagement with the outlet end **14** of the needleless syringe **12**, and the outlet end **64** of the housing **60** is in fluid communication with the receiving chamber **22**.

The valve member **70** has an inlet end **72** and a deformable body **74** both disposed within the housing **60**. The inlet end **72** is flush or substantially flush with the inlet end **62** of the housing **60** such that a deformable seal is defined and formed to limit or prevent contamination from entering the receiving chamber **22** through the fluid passageway **68**. If contaminating agents, such as dust, dirt, bacteria, viruses, or other potential contaminating agents, are externally present at or in the vicinity of the deformable seal, the deformable seal can be easily and effectively decontaminated or cleaned by swabbing the seal and the area in the vicinity of the seal with cleaning alcohol or other known cleaners or decontamination agents immediately prior to engaging the outlet end **14** of the needleless syringe **12** to the inlet end **62** of the housing **60**. The valve member **70** is biased to a closed configuration such that the fluid passageway **68** is closed from back flow of the

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fluids and administered fluid material from the receiving chamber **22**, and is movable to an open configuration such that the fluid passageway **68** is open to permit the fluid material administered by the needleless syringe **12** to flow through the fluid passageway **68** and to the receiving chamber **22**. It is preferred that the valve member **70** is resilient so that the inlet end **72** of the valve member **70** is able to still form a good seal with the inlet end **62** of the housing **60** after more than one administration of the fluid material.

As an example and shown in Fig. 1, the outlet end **14** of the needleless syringe **12** may consist of a centrally located tip **13**, and an internally threaded shield **15** surrounding the tip **13** such that the shield **15** is adapted to engage with the correspondingly threaded inlet end **62** of the housing **60**. The axial length of the tip **13** is greater than the axial length of the shield **15** such that the tip **13** makes contact with and pushes or moves the deformable body **74** of the valve member **70** to the open configuration when the shield **15** engages with the inlet end **62** of the housing **60**. Alternatively, the shield **15** may internally have a female luer fitting, or male luer fitting, adapted to engage with the male luer fitting (as shown in Fig. 3), or female luer fitting, respectively, of the inlet end **62** of the

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housing **60**. It is obvious to one in the art that the outlet end **14** of the needleless syringe **12** and inlet end **62** of the housing **60** may have correspondingly different engaging structures or configurations than the ones described above. It is also obvious to one in the art that the needleless administering device may be an adapter or connector that is connected, attached or secured to a syringe or device that can administer fluid materials.

As shown in Figs. 1-3, the handle **80** is integrally sealed to the top portion **34** of the I.V. solution bag **20**, and is adapted for hanging the receiving apparatus **10** upon the secured or standing structure **19**.

For simplicity and economical reasons, the I.V. solution bag **10** may be manufactured as a single unit. Also, the I.V. solution bag **10** may be manufactured of plastic, a polymeric material, and/or any other material known in the art. The valve device **50** may be manufactured by a molding or extrusion process.

It is to be understood that the present invention is not limited to the embodiment described above, but encompasses any and all embodiments within the scope of the following claims.

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